UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,518	09/23/2005	Martin F. Bachmann	1700.0630000/BJD/WBC	8347

26111 7590 09/25/2007

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,518	BACHMANN ET AL.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 8, 10, 14, 15, 32, 36, 37, 50, 53, 66, 69, 80, 82, 85, 96-99, 102, 107-109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-3,5,7,8,10,11,13-20,32,34-37,50,53,66,69,80,82,85,96-100,102 and 107-109.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,10,14,15,32,36,37,50,53,66,69,80,82,85,96-99,102 and 107-109.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, drawn to a composition of virus-like particle, and species election drawn to Qβ phage-HIV antigen, G8-8 SEQ ID No: 7, is acknowledged. Claims 1-3, 5, 11, 13, 16-20, 34, 35, 100 read on the elected invention. The traversal is on the ground(s) that a search of all pending claims can be made without serious burden. This is not found persuasive because it is maintained that each of the Inventions requires a separate search status and consideration. The inventions are mutually exclusive and independent products and methods that require different search criteria and technical considerations. The searches for different groups would have certain overlap, but they are not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02". Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of these inventions is not co-extensive, as indicated by the separate classifications. The requirement is still deemed proper and is therefore made **FINAL**.

However, as indicated previously, once the product claims are found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. In

the instant case, the methods of making and using the composition should be limited to packaging CpG ODN into the virus-like particle, and using the packaged VLP-ODN for vaccination in view of the preliminary amendment.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-3, 5, 7, 8, 10, 11, 13-20, 32, 34-37, 50, 53, 66, 69, 80, 82, 85, 96-100, 102, 107-109 are pending, however, claims 7, 8, 10, 14, 15, 32, 36, 37, 50, 53, 66, 69, 80, 82, 85, 96-99, 102, 107-109 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-3, 5, 11, 13, 16-20, 34, 35, 100 are under current examination.

Specification

The abstract of the disclosure is objected to because it does not commence on a sheet separate from other materials of the disclosure. Correction is required. See MPEP § 608.01(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5, 11, 13, 16-20, 34, 35, 100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-8, 10, 11, 42, 43, 47-49 of copending Application No. 10/243,739. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are encompassed by the claims of cited application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5, 11, 13, 16-20, 34, 35, 100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-207 of copending Application No. 10/244,065. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are encompassed by or overlapping with the claims of cited application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5, 11, 13, 16-20, 34, 35, 100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 13, 23, 25 of copending Application No. 10/465,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims encompass or overlapping with the claims of cited application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5, 11, 13, 16-20, 34, 35, 100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 10, 14-16, 4147, 48, 50, 52, 53, 54, 55, 57 of copending Application No. 10/563,994. Although the conflicting claims are not identical,

they are not patentably distinct from each other because instant claims encompass or overlapping with the claims of cited application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted the applicants have filed multiple applications that are co-pending and contain claims conflicting or overlapping in scope. For example, in addition to applications cited above, 10/550,580 and 11/397,830 also contain conflicting claims. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Citation of Relevant Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The claimed invention is drawn to a composition comprising a virus-like particle (VLP) and at least one unmethylated CpG-containing DNA oligonucleotide (ODN) flanked by less than 10 guanosine entities, which ODN is

packaged into said VLP, preferably an antigenic determinant is bound to said VLP.

A survey of prior art of record indicates that it was well known in the art to use VLPs such as modified HBV, HPV, and RNA phage Qβ as a carrier moiety for inducing immune response (*Gerber et al*, J Virol 2001;75:4752-60, IDS; *Kozlovska et al*, Intervirol 1996;39:9-15, IDS); it was also well known in the art to co-administer a CpG-containing oligonucleotide as an adjuvant for enhancing an antigen-specific immune response induced by VLP-mediated antigen presentation (*Gerber et al* J Virol 2001, IDS; *Storni et al*, J Immunol 2002 Mar 15;168:2880-6, IDS). The family of CpG ODN having a CpG as a part of a palindromic sequence flanked by less than 10 guanosine entities was known in the art as taught by *Hartmann et al*, (USP 6,949,520, SEQ ID Nos: 4 and 32, for example).

However, as stated in the specification, "This invention is based on the surprising finding that specific immunostimulatory substances such as DNA oligonucleotides packaged into VLPs renders them more immunogenic" (e.g. Specification, paragraph bridging pages 3-4). The significantly enhanced immunogenicity could be seen in a post-filing publication by the applicant (*Storni et al*, J Immunol 2004;172:1777-85), wherein figure 3 shows the VLP-ODN packaging group induced a significantly higher percentage of CD8+ T cells compared to the VLP+CpG-ODN co-administration group. Such effect would be difficult to predict based on the cited prior art of record.

Accordingly, it is concluded the prior art of record fails to anticipate or render obvious over instantly claimed invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants

can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
September 13, 2007